

## REMARKS

Claims 1-41 are currently before the examiner. Claims 7-12, 16-18, 25, 28-33 and 35-39 have been withdrawn by the examiner as, in the examiner's opinion, relating to a separate and distinct invention. Claims 1-6, 13-15, 19-24, 26, 27, 34, 40, and 41 have been rejected. Claims 1, 19, 21, and 40 have been amended to more accurately reflect that which the inventor considers the invention.

### **35 U.S.C. rejection of claims 1-6, 13-15, 19-24, 26, 27, 34, 40, and 41**

The examiner has rejected claims 1-6, 13-15, 19-24, 26, 27, 34, 40, and 41 as being anticipated by Chu, et al., U.S. Pat. No. 6,503,538. The ground relied on by the examiner for the rejection is that set forth in the Written Opinion of the International Searching Authority, which the examiner states she agrees with.

In the Written Opinion, the international examiner stated that:

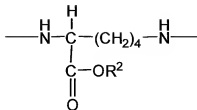
Document D1 (Chu) discloses elastomeric copolyester amides and methods for making the same. The biodegradation of the copolyester amides allows the delivery of essential  $\alpha$ -amino acids to targeted sites and can be used to coat stents. The polyester amide polymers can be used as carriers for various drugs.

The international examiner then states, based on the above, that the present application lacks novelty, which is akin to arguing under U.S. patent law that the application is anticipated, which is this examiner's position.

Applicant traverses.

### **Applicant's response**

The most obvious difference between Chu and the present invention is that the poly(ester amide)s used to coat stents are entirely different. That is, every one of Chu's disclosed poly(ester amide)s requires a constitutional unit having a pendent carboxy functionality:



wherein R<sup>2</sup> can be hydrogen or aralkyl (col 4, lines 1-16 and throughout the patent). Careful examination of the full range of poly(ester amide)s used in the claimed coatings for medical articles of the present invention reveals that there is no claim to a constitutional unit that contains or that might contain a pendent carboxyl group. Thus, Chu's poly(ester amide)s cannot and do not anticipate the poly(ester amide)s of the current invention and therefore cannot anticipate medical articles having coatings containing them.

The examiner is requested to reconsider and thereupon withdraw the rejection.

### Obviousness

While the examiner did not present an obviousness rejection in the instant office action, since the Written Opinion that was relied on by the examiner contains the international equivalent of such, i.e., a lack of inventive step argument, applicant will address the issue to hasten the allowance of the present invention. Thus, the Written Opinion contains the following:

3.1 The **problem** to be solved can be regarded as to provide improved coatings for drug delivery devices, such as drug eluting vascular stents, and methods for producing the same.

3.2 The **solution** is a medical device having a coating comprising specific polyester amide polymers and methods of producing the same.

3.3 D1, which may be regarded as the **most relevant prior art**, discloses elastomeric copolyester amides and methods of making the same. The biodegradation of the copolyester amides allows the delivery of essential  $\alpha$ -amino acids to targeted sites and can be used to coat stents. The polyester amide polymers can be used as carriers for various drugs (D1, column 10, line 32-33; column 10, line 43-55, bold emphasis in the original, underline added).

To render a claim obvious under U.S. patent law it is necessary to provide some rational basis upon which one of ordinary skill in the art would consider taking the step(s) necessary to achieve the claimed subject matter beginning from the prior art. KSR International Co. v. Teleflex, Inc. et al., 127 S.Ct. 1727 (2007). Here, the primary difference between the prior art, Chu, and the poly(ester amide)s of the coatings of the present invention is the presence of a pendent carboxyl functionality in all of Chu's polymers and the complete absence of such in the polymers of the present invention. Given the complexity of Chu's polymers and in view of the Chu disclosure, there is absolutely nothing, absent knowing of the present invention in advance, which would constitute impermissible hindsight, to cause one of ordinary skill in the art to consider removing the pendent carboxy group to arrive at a poly(ester amide) that might be similar to those of the current invention. In fact, quite to the contrary, one of skill in the art would be inclined to leave the carboxy group since Chu discloses its use to covalently link bioactive compounds to the polymer. That is, Chu states:

In addition, the polymers of the present invention can be used for the attachment free iminoxyl radicals (sic) for suppressing insoluble (sic) cell proliferation, and heparin or hirudin for increasing hemocompatibility. Col. 10, lines 28-32.

Chu even illustrates the above in Example 25, "4-AminoTEMPO attachment and its Bbiodegradation and Free Radicals Release Study," where Chu uses carbonyldiimidazole (col. 25, line 12-15), a standard carboxyl condensing agent, to create an amide linkage between the 4-aminoTEMPO (col. 25, line53-60) and a polymer of the invention. In this regard it is noted that the polymer structure provided with the example must be incorrect in that it does not contain the carboxyl group, which is present in all of Chu's compounds and which is necessary to carry out the amide-forming reaction. Thus, not only does Chu not anticipate the current invention, it fails to render it obvious as well.

### CONCLUSION

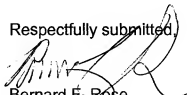
Based on the above remarks, applicant believes that this application is in condition for allowance and respectfully requests that it be passed to issue.

Applicant does not believe any fee is due with this response. If this is incorrect, the examiner is authorized to charge any amount due to Squire, Sanders & Dempsey Deposit Account No. 07-1850.

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Respectfully submitted,



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